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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,998	12/10/1999	NORMAN JAMES MOORE		9562

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/458,998

Applicant(s)

MOORE ET AL.

Examiner

Ja-Na A Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 10-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 10-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION
Amendment Entry

1. The amendment filed November 1, 2001 has been entered. Claims 1-9 have been cancelled. New claims 10-35 have been added. Claims 10-35 are pending in this office action.

Drawings

2. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicant's amendments and arguments:

a) the rejection of claims 1-3, 5-7 and 9 under 35 U.S.C. 103(a) as being unpatentable over Imrich et al.(US Patent 5,415,994) in view of Cuatrecasas et al. (US Patent 4,411,832) in further view of Strosberg et al (US Patent 4,780,407);

b) the rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Imrich et al.(US Patent 5,415,994) in view of Cuatrecasas et al. (US Patent 4,411,832) in view of Strosberg et al (US Patent 4,780,407) in further view of Yen et al. (US Patent 4,206,094);

c) the rejection of claims 8-9 under 35 U.S.C. 103(a) as being unpatentable over Imrich et al.(US Patent 5,415,994) in view of Cuatrecasas et al. (US Patent 4,411,832) in view of Strosberg et al (US Patent 4,780,407) and in further view of Jurgens et al.; and

d) the rejection of claims 1-9 under 35 U.S.C. 112, first paragraph.

New Grounds for Rejection
Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, claims 10(d) and 25(d) recite producing purified antigen specific antibodies. However the specification at page 5 paragraph 1, discloses using purified raw polyclonal antibodies. The specification further states that the use of unpurified raw antibodies provides poor results, thus the use of raw polyclonal antibodies is an essential element in the performance/ sensitivity of the assay. There is no support in the specification for the use of any purified antibody. There is only support for using the purified raw polyclonal

antibodies. Thus, the claims encompass new matter by not limiting the claims to the purified raw polyclonal antibody.

5. New claim 23 is drawn to concentration steps comprising high-speed centrifugation, decantation or aspiration, through stroking with a swab and delivering the sample to the receptacle. However, appears to be no teaching for these concentration steps. Applicant has not pointed to, by page and line number, in the specification for support. Thus, the amendment introduces new matter.

6. Claims 10-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for O-linked carbohydrate antigens produced under the specific recited conditions and the use of purified raw polyclonal antibodies, does not reasonably provide enablement for any protein-free carbohydrate antigen and any purified antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant claims are not limited to the O-linked carbohydrate antigens, but rather too protein-free carbohydrate antigens. Application 09/139,720 teaches detailed preparation of antibodies specific to O-carbohydrate antigens of *Legionella pneumophila*. The instant specification on page 4 at line 10-12 states that " applicants the developed a modified enzyme immunoassay ("EIA") using a coated tube in which *L. pneumophila* serogroup 1 raw polyclonal antibodies that have been purified according to the affinity purification procedure described and claimed in the parent application." See

also page 5 paragraph 1 of the instant specification. Therefore, the purified raw polyclonal antibodies and procedures disclosed in both 09/139,720 and the instant specification are what is being used in the instant application. Therefore, the claims of the instant application, need to claim the same O-carbohydrate antigens and purified raw polyclonal antibodies as described in the specifications. Claims 10-35 of the instant application fail to require the use the O-polysaccharide antigen sample or the use of purified raw polyclonal antibodies. Claims 10-35 of the instant application are not commensurate in scope with the examples taught in the specification of 09/139,720 or the instant specification.

The 09/139,720 specification requires conjugation and coupling of the O-polysaccharide antigen to the chromatographic column and further requires affinity purification of the antibodies to the O-polysaccharide antigen. The O-polysaccharide antigen must be present to create the antigen specific *Legionella* antibodies. Thus purified raw polyclonal antibodies recognizing the O-carbohydrate antigen of *Legionella* will bind and detect the presence of *Legionella*. However, the claims of the instant application do not recite the essential use of the O-carbohydrate antigen or the purified raw polyclonal antibodies.

Therefore, the claims do not include the limitations taught by the parent specification, thus they are not enabled.

7. Claims 10-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. In particular, claims 10 and 25 are unclear. Claims 10(e)(iv) and 25(e)(iv) disclose correlating an amount of O-carbohydrate antigen detected in the sample, however none of the previous steps recite using the O-carbohydrate antigen. The other steps within the claims fail to recite what specific antigen is being detected.

Furthermore, it is unclear if the antigen-specific antibodies bind only to an essentially protein-free carbohydrate antigen or to the O-carbohydrate antigen as produced in step (d) of claim 10 or step (f)(iv) of claim 25. It should be noted that the antibodies of 09/139,720 are specific to O-carbohydrate antigens of *Legionella*. Clarification is requested as to what the antibodies are specifically binding too.

It is also unclear whether the essentially protein-free carbohydrate antigen is the same antigen as the O-carbohydrate antigen, if so the terminology within the claims should be consistent.

8. Claims 11 and 26 are unclear is the recitation of "raw antibodies" The independent claims 10 and 25 do not recite raw antibodies. Thus, it is unclear if the raw antibodies are the same as the purified antigen-specific antibodies of step (d). If so, then consistent terminology is requested.

9. Claims 17 and 32 are unclear in the recitation of the test reaction vessel. It is unclear if the test reaction vessel in step (e)(iii) in claim 10 as the suitable reaction vessel. If so, then consistent terminology is requested.

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10. Claim 21 is vague and indefinite. Claim 21 recites the use of a buffer solution, however the claim does not disclose what reagents are encompassed within the buffer solution. It is unclear if this buffer solution is the same, as the extraction solution recited in 09/139,720, if so, then consistent terminology should be used throughout the claims and specifications.

11. Claim 23 says "a method according **the** claim 20" instead of according **to** claim 20. Appropriate correction is requested.

12. Claim 32 recites the use of a test reaction vessel in step (e)(iii) of claim 25, however claim 25 does not have a step (e)(iii). Appropriate correction is requested.

13. Claim 11 recites limitation "the raw antibody", claim 20 recites the limitation "the heating and/or cooling system", claim 21 recites the limitations "the test receptacle" and "the buffer solution" in the claim; and claim 35 recites "the buffer solution". There is insufficient antecedent basis for this limitation in the claim.

14. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: There is no contact step in step 25(e)(1) between the antibody coated particles and the carbohydrate antigens. The

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claim recites that the antibodies tend to draw to themselves carbohydrate antigen, however this is not a positive recitation step for contact between antibody and antigen.

Incorporation By Reference

15. The incorporation of essential material in the specification by reference to another patent application is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The attempt to incorporate subject matter into this application by reference to 09/139,720 is improper because the incorporation by reference attempts to incorporate essential material.

Double Patenting

16. Claims 10-35 of this application conflict with claims 69-100 of Application No. 09/139,720. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either

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cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 10-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 69-100 of copending Application No. 09/139,720. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in 09/458,998 are drawn to a method of determining the concentration of at least one species or serogroup of *Legionella* bacteria in water comprising the recited steps. While 09/139,720 is drawn to a method of detecting the presence of at least one group or serogroup of *Legionella* bacteria in a fluid sample comprising the same steps as recited 09/458,998. The method of determining the concentration of the *Legionella* (09/458,998) is inherently encompassed by the detection of the bacteria (09/139,720) when the same method steps are recited. Thus 09/458,998 is not patentably distinct from 09/139,720.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 

January 9, 2002


PATRICIA A. DUFFY
PRIMARY EXAMINER